REMARKS

CLAIM REJECTIONS - 35 U.S.C. §112

The Office has rejected claims 32, 33, and 68-73 under 35 U.S.C. §112, second paragraph, for allegedly omitting essential steps. (Office Action at 2.) Specifically, the Office notes that the omitted step is "how to modulate the neuronal transport of the tetanus toxin or the fusion protein and whether the neuronal transport is modulated." (Office Action at 2.) The Office then states: "The method step only refers [to] the administration of the TrkB agonist but *fails to refer back* to the preamble of the claimed method, i.e. modulating the transport in a neuron." (Office Action at 2)

In response to the previous Office Action, which also contained the same rejection by the Office, Applicant amended claim 32 by adding the term "thereby" before the term "modulate," in order to more distinctly point out the relationship between the addition of BDNF, NT-4, or GDNF and the modulation of the neuronal transport of tetanus toxin or the fusion protein. However, in the present Office Action, the Office remains unpersuaded and states, "[i]t remains unclear how and when the tetanus toxin or a fusion protein comprising a fragment C of the tetanus toxin is added to the neuron, and it is also unclear how to modulate the neuronal transport of the tetanus toxin or a fusion protein, *i.e.* how to detect the presence of tetanus toxin in the neuron." (Office Action at 2.) Applicant continues to traverse this rejection for the reasons of record as well as for the following additional reasons.

The second paragraph of 35 U.S.C. §112, under which the Office has rejected the claims, states:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The MPEP, at section 2171, sets forth two separate requirements for this statutory provision:

> (A) the claims must set forth the subject matter that applicants regard as their invention; and
>
> (B) the claims must particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant.

Applicant respectfully submits that the claims fully comply with these requirements.

With regard to requirement (A), there is no evidence of record that Applicant is claiming anything other than what she regards as her invention. Thus, the claims must be deemed to be in compliance with this requirement.

Applicant submits that the claims fulfill requirement (B) for the following reasons. With respect to the Office's concerns regarding how and when to add to a neuron, as well as how to modulate and detect in a neuron the tetanus toxin or a fusion protein comprising a fragment C of the tetanus toxin, Applicant first respectfully reminds the Office that base claim 32 recites: *A method of modulating the transport in a neuron of a tetanus toxin or a fusion protein comprising a fragment C of the tetanus toxin, wherein the method comprises administering to the neuron a Brain Derived Neurotrophic Factor (BDNF), a Neurotrophin 4 (NT-4), or a Glial-Derived Neurotrophic Factor (GDNF) in an amount sufficient to thereby modulate the neuronal transport of the tetanus toxin or the fusion protein.*

The method of modulating the transport in a neuron of a tetanus toxin, or a fusion protein comprising a fragment C of the tetanus toxin, as recited in base claim 32 is exemplified in at least Example 11 and Table 2 of the specification. (Specification at 36, paragraph 129.) In view of that Example and the data contained in Table 2, Applicant demonstrated that the addition of TrkB agonists, BDNF, NT-4, and GDNF, but not non-TrkB agonists, induced increased localization of a fusion protein comprising fragment C of the tetanus toxin at the neuromuscular junction (NMJ). Applicant courteously submits that one of skill in the art could have looked to at least Example 11 and Table 2 and found the teachings necessary to recognize that the modulation of the tetanus toxin, or fusion protein comprising fragment C of the tetanus toxin, as recited in claim 32 would have been a function of the administration of BDNF, NT-4, or GDNF.

One of skill in the art would have also recognized that the listing of steps in the claim relating to the addition and detection of tetanus toxin, or a fusion protein comprising fragment C of the tetanus toxin, would not be necessary to understand the metes and bounds of the claimed method. The addition of tetanus toxin or fragment C of tetanus toxin to neurons is well known in the art. *See* Schwab, ME and Thoenen H (1976) *Brain Res.* 105, 213-227. Furthermore, as tetanus toxin or fragment C of tetanus toxin are proteins, methods of detection are also well known in the art. These features are not germane to defining the metes and bounds of the subject matter Applicant seeks to patent.

In view of the foregoing arguments, Applicant respectfully requests that the rejection under 35 U.S.C. §112, second paragraph, be withdrawn.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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